Code of Practice for Applying for Ethical Approval at Anglia Ruskin University

Julie Scott
Research Ethics & Integrity Manager
Research and Innovation Development Office
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Version 7.10

If you require this Code of Practice in an alternative format (e.g. Braille, large print, Audio, Electronic) please contact the Research Ethics Committee Secretary on telephone number 01245 684640 or email address research.ethics@aru.ac.uk

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Introduction

This Code of Practice is designed to provide researchers with the key information they will need when applying for ethical approval from Anglia Ruskin University. It should be read in conjunction with our *Research Ethics Policy*, and with other documents as referred to below, which are available on the Research and Innovation Development Office (RIDO) website at: www.aru.ac.uk/researchethics, unless otherwise specified.

Research and innovation projects fall under this *Code of Practice.*

Applicants for ethical approval are required to declare that they have consulted the *Research Ethics Policy*, relevant sections of this *Code of Practice* and comply with the relevant data protection legislation as part of the ethics application process.

If you require this *Code of Practice* in an alternative format (e.g. Braille, large print, Audio, Electronic) please contact the Research Ethics Committee Secretary (contact details on next page).

Julie Scott,
Research Ethics and Integrity Manager
Research and Innovation Development Office
24 July 2019
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Frequently used acronyms

EEA – European Economic Area
FREP - Faculty Research Ethics Panel
GDPR -General Data Protection Requirement
HEI – Higher Education Institute
REC - Research Ethics Committee
RIDO – Research and Innovation Development Office
SREP – School Research Ethics Panel

Useful contacts

Research and Innovation Development Office

Job title	Name and email	Telephone
Research Ethics & Integrity Manager	Julie Scott research.ethics@aru.ac.uk	01245 684210
REC Secretary	research.ethics@aru.ac.uk	01245 684640

Faculty Research Ethics Panel (FREP) Chairs and Administrators

Faculty	Chair's name and email	Administrator's name and email
Arts, Humanities and Social Sciences (AHSS)	Dr Kofi Boakye kofi.boakye@aru.ac.uk	Emily Downing emily.downing@aru.ac.uk
Health, Education, Medicine and Social Care (HEMS)	Dr Sarah Burch sarah.burch@aru.ac.uk	Claire Mitchell claire.mitchell@aru.ac.uk
Faculty of Science & Engineering (FSE)	Professor Peter Bright peter.bright@aru.ac.uk	Sam Wilson samuel.wilson@aru.ac.uk
Business and Law (B&L)	Dr John Hogan john.hogan@aru.ac.uk	Corinne Mouhot-James corinne.mouhotjames@aru.ac.uk

Overview of Ethical Approval Requirements

1.1 What requires ethical approval?

The requirements for ethical approval outlined in this *Code of Practice* apply to all researchers, and to all types and stages of research and innovation.

UK Research and Innovation do not distinguish between the two and therefore Anglia Ruskin University has decided that innovation projects also fall under this *Code.* For the purposes of succinctness, the term 'research' will be used throughout the *Code.*

Our *Research Ethics Policy* defines the term 'researcher' to mean **all students and staff** of Anglia Ruskin University who are undertaking research, including **students at our Franchised Associate Colleges.** In addition, it includes anyone involved in conducting research with Anglia Ruskin University, whether on or off our premises or in collaboration with our staff and/or students, including on a consultancy basis. This includes those doing research on a collaborative basis, even if another institution is the lead Higher Education Institute and individuals who are neither employed by or students of Anglia Ruskin University, who are conducting research on our premises or under our auspices.

For the small number of our Associate Colleges **not covered by a Franchise agreement** e.g. with whom we have dual award and validation arrangements, it has been agreed that, in general they can follow their own ethics procedures, subject to approval by the relevant Anglia Ruskin committees.

Not all parts of this document are applicable to students at Franchise Associate Colleges e.g. Risk Assessment requirements and insurance arrangements. Students who are unsure of the nature of their college's agreement with Anglia Ruskin should consult their Supervisors.

For research where **all the students on a course will be carrying out research that falls under the Green ethical risk category** (see Section 2.2), the Course Leader can ask for an exemption from the ethical approval process (this then needs to be confirmed by the relevant Faculty Research Ethics Panel Chair and approved by the Academic Registry). Students are not required to complete ethics application forms and training.

Please note that postgraduate research students complete an ethics checklist on Progress Platform when they submit their research proposal. This **does not** constitute applying for ethical approval. It is also recognised that responses given on this checklist may have changed by the time the student applies for ethical approval.

Anglia Ruskin's ethical approval does not automatically cover collaborators at other institutions. In cases where Anglia Ruskin is the Lead Institution, you need to ensure that collaborators have checked their own ethical approval and insurance arrangements and confirm this in your ethics submission. Where another institution is the Lead, you need to check with your Faculty Research Ethics Panel (FREP) Chair if further approval is required from Anglia Ruskin and also check your own insurance arrangements (please contact Andy Chapman, Corporate Risk and Compliance Officer, on email address andrew.chapman@aru.ac.uk).

Certain external ethical approval may be recognised as equivalent to our own (e.g. NHS, Ministry of Justice and Ministry of Defence Research Ethics Committees and Social Care) and in such cases the researcher may not be obliged to make a full application for ethical approval to Anglia Ruskin; see Section 2.5 and the relevant Sections in Part 3. It is your responsibility to obtain research ethics and/or governance approval from any external agencies and check with your FREP whether ethical approval is also required from Anglia Ruskin.

Where an external researcher who has obtained ethical approval from their own Higher Education Institution wishes to carry out research involving our staff, students or premises, we will accept evidence of the ethical approval obtained as equivalent to our own wherever possible. In the first instance, please send the relevant Faculty Research Ethics Panel (FREP) Chair or the Research Ethics and Integrity Manager all the documents submitted to the other Higher Education Institution and the ethical approval received from them. This documentation will then be reviewed and a decision taken. We will also require confirmation of the indemnity arrangements for the researcher(s). Please note that you cannot start your research until you receive confirmation from an appropriate person at Anglia Ruskin that you can go ahead with it.

1.2 Why does research require ethical approval?

As part of good research governance, research requires ethical approval. This is:

- because a consideration of the ethical issues is likely to help you think about the stages of your research more carefully
- to avoid potential problems later on, by ensuring that the main foreseeable ethical issues are addressed before the research starts
- to protect the rights and welfare of participants and minimise the risk of physical and mental discomfort, harm and danger from research procedures
- to protect your rights as a researcher to carry out legitimate investigations
- to protect the reputation of Anglia Ruskin University in respect of research conducted by its students and staff
- in order that you are insured to carry out your research
- to minimise the potential for claims of negligence made against you, Anglia Ruskin University and/or any collaborating individual or organisation
- because refereed journals increasingly require evidence of ethical approval before they will publish your work.

1.3 When should I start thinking about ethical approval?

You should start to consider ethical issues at the earliest possible stage in planning your research. A proper consideration of ethical principles is relevant to, and will almost certainly influence, fundamental aspects of the research design from research methods to sampling. The Faculty Research Ethics Panel (FREP) or School Research Ethics Panel (SREP) will want to be assured that you have thought about all aspects of your research and addressed potential risks and ethical issues.

You must also allow sufficient time for necessary consultation as part of the ethical review process. Changes may be needed to your application, which then needs resubmitting. Finally, some studies will need other permissions or approvals, which can also take time to obtain (please refer to Section 3).

If you will need a Disclosure and Barring Service Check (please refer to Section 3.1 of this Code of Practice) or any other permission that could take a while to obtain, you need to start the process well in advance of submitting your ethics application.

1.4 Research involving animals or significant habitats

Anglia Ruskin University does not hold licences under the Animals (Scientific Procedures) Act (1986) and therefore anything that constitutes a procedure under that Act is not permitted. If researchers are involved in collaborative work falling under A(SP)A, approval must be sought through the collaborating organisation, and take place on their premises under their licences.

Most research in Anglia Ruskin University therefore has little or no direct impact on animals or significant habitats. Where it occurs, please note that a specific version of the Stage 1 Research Ethics Application Form must be completed (Stage 1 Research Ethics Application Form involving Animals and Habitats), which is usually reviewed within the Life Sciences SREP or the Faculty of Science & Engineering FREP. Please speak to your Supervisor or contact the SREP or FREP if you are not sure where to submit your application.

1.5 Research involving human material

The Human Biological Material Committee (HBMC) must be notified of all research with human material you are planning to carry out, regardless of whether it falls under the Human Tissue Act (2004), for example, serum that does not contain cells or material created outside of the body, such as cell lines. This includes the genetic modification of human tissue.

For research that does fall under the Human Tissue Act (2004), when it is in the remit under one of Anglia Ruskin's Research Licences from the Human Tissue Authority, it can be reviewed by either the Health, Education, Medicines and Social Care or Science and Engineering Faculty Research Ethics Panel (FREP). Following ethical approval, the FREP will refer your research to the Human Biological Material Committee (HBMC), which needs to also approve research involving human tissue, as parts of our requirements under the Human Tissue Act (2004).

If the research does not fall under our Licence, it can only legally be reviewed by an NHS Research Ethics Committee. Please contact the Human Biological Materials Committee on ARU-HBMC@aru.ac.uk if you have any queries and also to let them know that your research is being reviewed by an NHS REC.

Also see Sections 3.2 and 6.6.

1.6 Research involving genetically modified organisms

You must contact FST-Biologicalsafety@GMO@aru.ac.uk for information if your research involves the use of genetically modified organisms.

Prior to obtaining ethical approval for this type of study, a Risk Assessment needs to be completed and approved before any GMO work can begin. Please contact the above email address for advice.

The Risk Assessment is required under the Genetically Modified Organisms (Contained Use) Regulations (2014), to determine the classification of your research. Anything other than a Class One assessment (no or negligible risk) carries various additional requirements for notification and approval before the proposed research can start.

1.7 Research involving people who lack capacity

University research ethics committees cannot legally approve any research with people aged 16 years and above, who do not have capacity to consent. For further information, refer to Section 6.2.

1.8 Pilot studies

If you intend to carry out a pilot study, you must obtain ethical approval for it first. Any research to follow up the pilot study will also require ethical approval if you have made changes to your study as a result of the pilot. This includes any changes to the responses you previously provided in the Research Checklist for Data Protection or in the Stage 1 Research Ethics

Application Form regarding the use of special category data or the intention to recruit 100 or more participants.

Should your research use a questionnaire of your own devising, it is strongly recommended that you pilot it first. Ethical approval will be required for the pilot study and any changes to the questionnaire following it will also need ethical approval. Please make it easy for the ethics committee to identify revisions (for example by using track changes).

1.9 Collaborative research

If you are engaged in collaborative research where another HEI is the Lead Organisation, we may accept their ethical approval as equivalent to our own. You need to send the relevant FREP or the Research Ethics and Integrity Manager a copy of the ethics application and approval notification from the lead HEI and wait for permission to proceed.

Where Anglia Ruskin is the Lead HEI, you need to obtain ethical approval from the relevant FREP/SREP. You need to check that other collaborators have obtained ethical approval from their own institution if required and clarified their insurance arrangements. Alternatively, ethical approval may be conditional on ethical approval being obtained from collaborating HEIs if required. In your application for research ethics approval you must list the collaborating researchers and their HEIs.

1.10 Reuse of previous research data

You may be able to reuse data obtained from previous research. You will need to check that ethical approval was obtained and that participants gave appropriate permission for the data to be reused in the way that you intend. Please also contact our Data Protection Officer at dpo@aru.ac.uk to clarify that the reuse of data is in compliance with data protection legislation, should this not be completely clear. There may also be copyright and/or intellectual property issues to consider. If you wish to reuse data, you are advised to seek guidance from your Supervisors and/or the relevant FREP/SREP Chair at the earliest opportunity.

Please also refer to the Concordat on Open Research Data:

https://www.ukri.org/files/legacy/documents/concordatonopenresearchdata-pdf/

1.11 Conflicts of interest

If there are any conflicts of interest, these must be declared in the ethics application. This includes a conflict of interest arising from the funding for the research.

1.12 Compliance with ethics procedures

Researchers are required to fully participate in the ethical review process. Failure to comply with our ethics procedures and any conditions specified is subject to investigation under Anglia Ruskin's *Guidance for the Investigation of Allegations of Misconduct in Research.*

Anglia Ruskin University *has a Good Research Practice Guide and* supports the *Concordat to Support Research Integrity.*

The above are accessible at:

http://web.anglia.ac.uk/anet/rido/ethics/about/researchintegrity.phtml

1.13 Research outside the remit of a student or member of staff at Anglia Ruskin

If research is outside the remit of someone's role, as a student or member of staff at Anglia Ruskin, we cannot give it ethical approval, due to indemnity issues. This also means that the researcher will not be permitted to use Anglia Ruskin's name (or the name of their institution) in dissemination.

How to Apply for Anglia Ruskin University Ethical Approval

2.1 All applications

All documents are available on the research ethics website at www.aru.ac.uk/researchethics

All applicants should complete Sections 1 and 2 of the Stage 1 Research Ethics Application Form or, if applicable, the Stage 1 Research Ethics Application Form involving Animals and Habitats.

Section 3 of both versions of the Stage 1 Research Ethics Application Form contains a flow chart which will determine which risk category your proposed research falls into, labelled by colour. This classification determines whether further ethical approval is required, the application requirements and nature of that approval. For further information on the requirements for each risk category, please see below.

Applicants whose research involves personal data will need to refer to Section 5: Data Protection on the Stage 1 Research Ethics Application Form. This is very unlikely to apply to any research falling under the 'green' category. If your research will involve the European Economic Area, you need to complete the *Research Checklist for Data Protection*.

https://web.anglia.ac.uk/anet/staff/sec_clerk/Data%20Protection/guidance/research.phtml

A definition of 'personal data' is:

Personal data means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person**.**

If you say 'yes' to Question 29 on the Stage 1 Research Ethics Application Form (or Question 39 on the Stage 1 Research Ethics Application Form involving Animals or Habitats), regarding whether your research will involve special category data or you intend to recruit 100 or more participants, you also need to complete *Further Data Protection Questions,* which is available at.

If you are able to confirm all the statements on the *Further Data Protection Question*s form, you need to submit it with your ethics application. If this is not the case, you must send it to the Data Protection Officer at dpo@aru.ac.uk in order that a decision can be reached regarding whether a Data Protection Impact Assessment is required. This must be resolved before you submit your application for ethical approval. You must submit all documents and correspondence relating to this with your ethics application. For further information about data protection, please refer to the Question Specific Advice for the Stage 1 Research Ethics Application Form and the other data protection guidance on the research ethics website at www.aru.ac.uk/researchethics

For any queries regarding data protection, please email our Data Protection Officer at dpo@aru.ac.uk

https://web.anglia.ac.uk/anet/staff/sec_clerk/Data%20Protection/guidance/research2.phtml

All applicants, for all risk categories, are required to complete the confirmation statements in Section 6 of the Stage 1 Research Ethics Application Form that:

a. they have completed any relevant training in research ethics required of them (see Chapter 4).

b. they have consulted the Anglia Ruskin *Research Ethics Policy*, and the relevant sections of this *Code of Practice.*
c. they have completed a Risk Assessment (Health and Safety) if applicable (see Section 3.13).
d. they have completed the Research Checklist for Data Protection or, for research that does not involve the European Economic Union (EEA), they will comply with any data protection legislation of that country or countries.
e. they have completed a Project Risk Assessment, if their research is funded externally and was acquired via Anglia Ruskin (see Section 3.14).
f. they have completed the online Safeguarding course, if applicable (see Section 4.4).
g. that if the research project involves a contract between Anglia Ruskin University and an external party, they have had the contract approved by the Secretary and Clerk's Office.

Please make sure that you have proof read your application and any accompanying documents before submitting them.

2.2 Green ethical risk category

Applicants do not need to complete Section 4 (Project Details) or Section 5 (Data Protection) of the Stage 1 Research Ethics Application Form, but must complete:

a. Section 6 (Confirmation/Declaration Statements)

Undergraduate and Masters students must also submit, in addition to making a declaration that they have completed it:

b. confirmation of passing the online course, *Introduction to Research and Professional Ethics* (please refer to Section 4.1).

Students must send the completed application to their Supervisors for review. This includes members of staff who are carrying out research in the capacity of a student. Supervisors are responsible for forwarding students' applications to the relevant SREP, for their records only.

Staff not doing research in student capacity should send the completed application directly to the relevant SREP (for that panel's records only).

Anglia Ruskin University ethical approval is *not* required.

You may, however need other permissions and approvals, not related to ethics approval, before you can commence your research. These are discussed in Section 3. Having completed these steps, you can start your research.

A sample of 'green' applications will be audited each year by the FREP Chair.

2.3 Yellow ethical risk category

All applicants must submit:

a. Stage 1 Research Ethics Application Form with all sections (including Section 4: Project Details completed
b. a Participant Information Sheet (if applicable to the research)
c. a Participant Consent Form (if applicable to the research)

All applicants carrying out research with children or vulnerable adults must also submit:

d. confirmation of passing the Safeguarding course if applicable (see Section 4.4).

Undergraduate and Masters students must also submit, in addition to making a declaration that they have completed it,

e) confirmation of passing the online course, *Introduction to Research and Professional Ethics* (please refer to Section 4.1).

Some Faculties may ask for additional documents as part of the application. Please check requirements with your Supervisor.

Students must send the completed application to their Supervisor for review, including staff carrying out an award in a student capacity. In turn, Supervisors are responsible for forwarding students' applications to the relevant SREP.

Staff not carrying out research in a student capacity should send the completed application directly to the relevant SREP for ethical review.

Ethical review, proportionate to the risk involved, is required for research falling into the yellow ethical risk category. You must wait for Anglia Ruskin University ethical approval before you can start your research. However, you may also need other permissions and approvals, not related to ethics approval, before you can commence your research. These are discussed in Section 3. Having completed these steps, you can start your research.

2.4 Red ethical risk category

Applicants do not need to complete Section 4: Project Details of the Stage 1 Research Ethics Application Form, but do need to submit:

a. Stage 1 Research Ethics Application Form
b. Stage 2 Research Ethics Application Form
c. a Participant Information Sheet (if applicable to the research)
d. a Participant Consent Form (if applicable to the research)
e. any questionnaires or interview schedules
f. any approved instruments or measures to be used
g. any advertising materials to be used to recruit participants
h. any ethical approval required for overseas research
i. power calculations for any experimental studies
j. any other documents you intend to use in your research.

All applicants whose research relates to terrorism must store their research in a secure online store set up by Anglia Ruskin

Please contact Julie Scott, Research Ethics and Integrity Manager at julie.scott@aru.ac.uk at the earliest opportunity to ask for the store to be set up.

Please see Sections 6.4 and 6.5 of this *Code of Practice and the Guidance for Security Sensitive Research f*or further information.

All applicants who say 'yes' to Question 23 on the Stage 1 Research Ethics Application Form or Question 34 on the Stage 1 Form for Research involving Animals or Significant Habitats (risk being construed as encouraging terrorism…), must also complete:

k. the Stage 3 Research Ethics Application Form

All applicants carrying out research with children or vulnerable adults may also need to submit:

l. confirmation of passing the Safeguarding course (see Section 4.4).

Undergraduate and Masters students must also submit, in addition to making a declaration that they have completed it:

m. confirmation of passing the VLE-based ethics training quiz (see section 4.1).

Some Faculties may ask for additional documents as part of their application. You will be informed of any such requirements.

Students must send the completed application to their Supervisors for review. Supervisors are responsible for forwarding students' applications to the relevant FREP.

Staff not carrying out research in a student capacity should send the completed application directly to the relevant FREP.

Ethical review is required for research falling into the red ethical risk category, which is classified as higher risk. You must wait for Anglia Ruskin University ethical approval before you can start your research. However, you may also need other permissions and approvals, not related to ethics approval, before you can commence your research. These are discussed further in Section 3. Having completed these steps, you can start your research.

2.5 Purple ethical risk category

Research falling into the purple ethical risk category requires external ethical and/or governance approval, which may be regarded as equivalent to that from Anglia Ruskin University. Please refer to Section 3 for further information regarding this and the approval that is considered to be equivalent to our own. In cases where the approval is not regarded as equivalent to our own or constitutes a governance as opposed to ethical review, you also need to obtain ethical approval from Anglia Ruskin.

- If ethical approval from the other organisation is regarded as equivalent to Anglia Ruskin, you must complete the Stage 1 Research Ethics Application Form (omitting Section 4: Project details) with all the documents you submitted to the external organisation followed by their approval when you receive it and wait for confirmation of receipt from the FREP Chair.
- If ethical approval from Anglia Ruskin is required, you must follow the process for research in the 'red' category, detailed in Section 2.4, above.

Students must send their completed applications immediately to their Supervisors for review, who then forward this to the FREP. Staff not carrying out research in a student capacity must send the applications directly to their FREP.

There are further requirements if Anglia Ruskin University is acting as a Sponsor, as defined by the Department of Health. Researchers may also need an NHS Research Passport. Please refer to Sections 3.3. and 3.4 respectively.

You may also need other permissions and approvals, not related to ethics approval, before you can commence your research. These are discussed further below, see Section 3. Having completed these steps, you can start your research.

2.6 Documents required to support your research ethics application

Depending on the ethical risk category into which your research falls, you may be required to submit additional documents, as outlined above, in support of your application.

Please ensure that you have submitted all the relevant documents, as without these your application cannot be considered, and you will be unable to start your research.

Where you are required to provide documents that you will use as part of your research, those that you submit must be the ones you will use. If you subsequently make any changes to your research you must submit an amended application (see Section 2.10 below).

2.7 Participant Information Sheet and Consent Form

A Participant Information Sheet is essential to inform participants about your research study. There is a template for this on the research ethics website that Undergraduates and Masters students are strongly advised to use.

The Participant Information Sheet should briefly explain what your research is about and intended to achieve, what you are asking participants to do if they choose to participate and how you will use the data that participants provide. For example, if you are intending to record interviews, or use quotations in your report that increase the chance that individuals will be identified, you must mention this, and you must describe how you will store and when you will destroy, the data you collect.

You must also make it clear if there are any potential benefits or risks to participating and state that your research has ethical approval from Anglia Ruskin University. Participants have the right to withdraw at any time without providing an explanation and the Participant Information Sheet should inform of this, and that participants are not obliged to participate fully, for example they may refuse to answer a question if they do not wish to do so. Participants must also be informed about their legal rights.

You must provide contact details to allow participants to request any further information; this should normally be your Anglia email address. You should not give a personal email address or landline telephone number, but mobile numbers are acceptable if there is no alternative.

You should encourage participants to speak to you or your Supervisor in the first instance if they have any concerns, but you should also provide details of the Anglia Ruskin University complaints procedure:

https://web.anglia.ac.uk/anet/staff/sec_clerk/Complaints/feedback.phtml

Students from our Associate Colleges must include the contact details of their own complaints departments.

If you are based in the European Economic Area (EEA), you also need to provide information to comply with the General Data Protection Requirement (GDPR) and for those also in the UK, the Data Protection Act (2018). The GDPR also applies if you are carrying out research outside of the EEA but bringing data back into it. For those based outside the UK, you need to also comply with any other data protection legislation in that country. The information you need to include on your Participant Information Sheet is available on the research ethics website at:

www.aru.ac.uk/researchethics

It is also incorporated into the above mentioned template Participant Information Sheet that Undergraduates and Masters students are strongly advised to use.

The Participant Consent Form is used to confirm the participant's agreement to participate in your study. Please note, however, that gaining consent must be viewed as a process, not just the participant reading a Participant Information Sheet and signing a Consent Form. If there is any doubt whether a participant can give fully informed, voluntary consent you must not proceed with them as participants in the research. Although you would normally obtain written consent, in some contexts this may not be appropriate or possible, for example due cultural norms. . In such circumstances it is acceptable to take consent in another way (e.g. you may do this verbally if recording interviews) but you need to explain on your application why you are doing this. Issues around consent are discussed further in Section 5.3.

There is a template Participant Consent Form on the ethics website. Undergraduate and Master's students are advised to follow this.

In preparing both documents, you should use clear and accessible language and only the most necessary technical terms. Try to avoid abbreviations. You will need to adapt your Participant Information Sheet to address the needs of different participants, for example younger children, people who may require the information in alternative formats, or where cultural differences may have an influence, particularly if doing the research outside the UK. You are advised to show your Participant Information Sheet and Consent Form to someone outside of your field to see if they are able to understand them; you may also find it useful to carry out a readability analysis, for example using the Flesch Reading Ease Readability Formula, at:

http://www.readabilityformulas.com/flesch-reading-ease-readability-formula.php

Your participants should be given a copy of your Participant Information Sheet and Consent Form to keep.

2.8 Ethics committee structure and decision-making outcomes

All Faculties have School Research Ethics Panels (SREPs). Some of our Franchise Associate Colleges have devolved SREPs.

All SREPs report to their respective Faculty Research Ethics Panel (FREP), including devolved SREPs which report to the relevant Faculty. Decisions of SREPs are subject to ratification by their FREP.

At institutional level, the Research Ethics Committee (REC) deals with policy and procedure. REC is a sub-committee of Research and Innovation Committee, which is itself a Standing Committee of Senate.

Terms of reference for REC, FREPs and SREPs are set out in the *Constitution of the Academic Committee Structure* at: https://web.anglia.ac.uk/anet/academic/public/constitution.pdf

REC delegates ethical review to the SREPs and FREPs, which are therefore responsible for the operation of our Research Ethics approval requirements. Possible decisions of FREPs/SREPs are normally:

- approve outright
- offer approval subject to certain conditions
- request specific revisions, which may be approved by Chair's Action or the full committee
- request a full resubmission, in cases in which the application requires extensive rewriting)
- referral to another SREP or FREP seen as better able to make a decision, or to the parent FREP or (exceptionally) REC
- reject outright.

SREPs/FREPs may also make other general conditions which will be listed on your approval letter, with which you must you comply. Faculty-specific information about FREPs is at:

http://web.anglia.ac.uk/anet/rdcs/ethics/about/frep.phtml

Supervisors who are members of a SREP or FREP must not take a part in the consideration of their students' applications.

2.9 Extensions to your ethical approval period

All ethical approvals are valid for a specific period of time (normally one year for Undergraduate and Masters students and three years for postgraduate research students and staff). Please ensure that if you need an extension you apply for this in sufficient time and before your approval expires. Retrospective ethical approval is not possible.

If you are not intending to make any changes to your study, you do not need to submit a new application. Please instead email the SREP or FREP which gave you ethical approval to request an extension. You cannot proceed with your study after the original approval has expired until you have confirmation from your FREP/SREP. An extension to your research can be given for a year; please apply to your FREP/SREP again if you will need further time after this.

Data Protection

Please note that, if your research involves the European Economic Area (EEA), including collecting data outside the EEA and bringing it in, you must check that:

- your responses on the *Research Checklist for Data Protection* remain the same. If not, please contact our Data Protection Officer.
- your response to Question 29 on the *Stage 1 Research Ethics Application Form* (Question 39 on the S*tage 1 Research Ethics Application Form involving Animals and Habitats*) regarding special category data and 100 or more participants has not changed from 'no' to 'yes'. If it has, you need to complete the *Further Data Protection Questions and* contact our Data Protection Officer should your research not comply with any of these.
- Should you have previously completed the *Further Data Protection Questions,* please check whether the responses to these remain the same. If there are any changes, please contact our Data Protection Officer should your research not comply with any of these.
- Email address for Data Protection Officer: dpo@aru.ac.uk

2.10 Amendments to your approved study

If you wish to make any amendments to your study, you must apply for re-approval. If these changes are minor, you should explain them by email to the administrator responsible for the FREP/SREP which originally approved it. More substantial changes require a resubmission of your ethics application to the committee which originally considered it.

You must follow the procedure detailed above in Section 2.9 with regards to data protection.

Please ensure that it is clear how you have revised your research. You may wish to do this in a separate commentary. You should also indicate any previous re-approvals.

You must wait for approval before you implement your changes and continue with your research.

The expiry date of your approval will remain as previously (Undergraduates and Masters students are given approval for a year and Doctoral Students for three). If you wish to apply for more time, refer to Section 2.9.

2.11 Adverse events and 'near misses'

Any accidents and 'near misses' which occur during the research must be reported to a member of the Risk Management team immediately, via riskmanagement@aru.ac.uk or on 01245 684239. For further information, please see the Risk Management website:

https://web.anglia.ac.uk/anet/staff/sec_clerk/RiskManagement/Welcome.phtml

You must also report any other adverse incidents or events relating to the research to the FREP/SREP within two working days of their occurrence.

2.12 Data Protection breaches

Our Data Protection Officer must be informed of any personal data incidents immediately at: dpo@aru.ac.uk

Incidents are defined as: accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to personal data transmitted, stored or otherwise processed.

The University is required to notify the Information Commissioner's Office of personal data breaches within 72 hours where they pose a risk to the rights and freedoms of the data subjects and so there must be no delay in initiating a formal review of an incident's severity. The GDPR has introduced significant fines for personal data breaches.

Students from Associate Colleges need to check who their own Data Protection Officer is.

2.13 Notification regarding end of project

When your study has ended, please ensure that you notify your FREP/SREP Administrator.

2.14 Monitoring

Your research project may be subject to monitoring. To enable you to meet the requirements for this, please keep copies of all the documentation relating to the study and evidence of the original ethical approval and any subsequent approval for amendments.

Our Data Protection Officer will also audit a sample of Participant Information Sheets, to ensure compliance with data protection legislation.

2.15 Complaints

Complaints or expressions of concern about the research ethics processes at Anglia Ruskin University can be made through the Office of the Secretary and Clerk via complaints@aru.ac.uk.

Any complaints arising from research activity should be dealt with through the appropriate Anglia Ruskin University procedures. Information on the complaints procedure may be found at: https://web.aru.ac.uk/anet/staff/sec_clerk/Complaints/feedback.phtml

Students from Associate Colleges need to check what their own procedures for complaints are.

Other permissions, approvals and requirements to consider

You may also need to consider other requirements, including obtaining other approvals or permissions before commencing your research, regardless of the ethical risk category your research falls into. It is **your responsibility** to obtain and consider these. In some cases, as outlined above, the FREP/SREP may request confirmation that specific permissions or approvals have been obtained, or requirements considered, but you should not rely on this.

If your research falls under legislation, the FREP/SREP will want to see that you are familiar with the legislation and evidence that you will adhere to it. It is also your responsibility to be aware of any legislation that comes into force during your research. If this requires further changes to your research, you must apply for approval for these revisions, as with any other amendments (see Section 2.10).

The following list of other permissions, approvals and requirements are not an exhaustive list. It is your responsibility to ensure that you are aware of all approvals and permissions required and obtain them.

3.1 Disclosure and Barring Service (DBS) check

Some research involving children and adults will require a Disclosure and Barring Service (DBS) check.

Please note that this doesn't automatically apply to all research involving children or vulnerable adults.

For any queries regarding whether you need a DBS Check, please email DBSOfficer@aru.ac.uk (students) or contact your HRS representative (staff).

Please see the DBS website:

https://www.gov.uk/dbs-update-service

Students should refer to the DBS14F Initial Guidance and Continuous Consent Forms available on the Research Ethics website.

Staff should check the Criminal Convictions, Disclosures and Barring Policy to establish whether their research will require a DBS Check, available at:

https://web.anglia.ac.uk/hr/staffarea/public/Staff%20Criminal%20Convictions%20Disclosures%20and%20Barring%20Policy.pdf

and speak to their designated HRS Manager.

Please seek advice from your Faculty as to whether the costs of your DBS check can be covered or whether you will need to pay the fee yourself.

If you are conducting your research in the UK and any of your participants are younger than 18 years of age, and/or are considered as vulnerable, you are required to confirm in your ethics application whether a DBS Check is required and if so, whether you are applying for one. Ethical approval cannot be given until it is confirmed that you have a satisfactory DBS Check if this is required.

If you have recently moved to the UK, you will also be required to produce a Certificate of Good Conduct.

If you are currently based in the UK, but travelling overseas to conduct your research, you will need to obtain a DBS certificate and also any equivalent clearance for that country if it exists. If you are both located and conducting research outside the UK, you need to obtain the equivalent clearance for that country, if it exists. You may also be required to obtain a letter from either the British High Commission or a local constabulary confirming that you have no criminal convictions.

3.2 NHS and Social Care approvals

The Health Research Authority (HRA) is the new process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent REC opinion provided through the UK Health Schools' Research Ethics Service. It replaces the need for local checks of legal compliance and related matters by each participating organisation in England. This allows participating organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study.

In the first instance, you need to contact the R&D Office at each Trust where you will be doing the research to see if they are happy to support your research.

http://www.rdforum.nhs.uk/content/contact-details/

If your research requires HRA Approval, NHS Research Ethics Committee Approval and a R&D Cost and Capacity Check, this approval will be regarded as equivalent to our own, but you will need to complete a Stage 1 Research Ethics Application Form and submit to your FREP for their information.

If your research requires HRA Approval and/or a R&D Cost and Capacity check, but not NHS Research Ethics Approval, you will need to obtain the ethical approval component from your FREP.

For further information, and to see what HRA/NHS approvals your research might require, see:

http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/assessment-approval/

https://www.myresearchproject.org.uk/help/hlphraapproval.aspx

Health and Care Research Wales is aligning its processes and paperwork so that there is consistency across England and Wales for researchers. This change is part of an incremental approach in Wales to implementing the local information pack across the UK. Please see:

https://www.hra.nhs.uk/about-us/news-updates/health-and-care-research-wales-align-processes-across-england-and-wales/

Please also refer to the information about improving consistency across cross border research in the UK.

https://www.hra.nhs.uk/about-us/news-updates/improving-consistency-cross-border-research-within-uk/

Certain kinds of research taking place in the NHS may fall under the criteria for proportionate review, rather than a full review. Please see:

http://www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-proportionate-review-service/

Research falling under the Human Tissue Act (2004) can only be reviewed by an Anglia Ruskin ethics committee if it falls under the terms of our Research Licence from the Human Tissue Authority. Otherwise, it can only be reviewed by 'a research ethics authority', i.e. any ethics committee recognised by the United Kingdom Ethics Committee Authority (UKECA) under the Clinical Trials Regulations, or any REC recognised by the Health Schools in England, Wales or Northern Ireland to advise on the ethics of research involving human tissue. Please see:

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/use-tissue-research/

Please note that if you need to obtain NHS REC Approval for your research involving human tissue, you must also notify the Human Biological Material Committee at ARU-HBMC@aru.ac.uk

Anglia Ruskin's ethics committee cannot review research that falls under the Mental Capacity Act (2005). This research can only legally be reviewed by a Research Ethics Committee recognised by the Secretary of State or Welsh Ministers.

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/mental-capacity-act/

or the National Social Care Research Ethics Committee; please see.

http://www.hra.nhs.uk/resources/before-you-apply/non-nhs-recs/national-social-care-research-ethics-committee/

For research involving social care (e.g. councils) please first check with the organisation regarding whether they have their own system for ethics/governance review or whether you need to apply to the National Social Care Research Ethics Committee for approval. Please refer to the above web-link for information about the National Social Care Research Ethics Committee.

In cases in which a research governance review only is carried out you are also likely to need to apply for ethical approval from a FREP at Anglia Ruskin. Please contact your FREP Chair in the first instance and send them the application form, any other documents submitted to the other organisation(s) and the approval letter if you have obtained this. You need to ask the FREP Chair whether this approval can be accepted as equivalent to our own ethical approval and wait for clarification on this before you start your research.

You must also comply with any other requirements, policies and procedures of the Health Research Authority, NHS and Social Care organisations. Please also see Sections 3.3 and 3.4 about Sponsorship and the NHS Research Passport Scheme.

Please note that it is your responsibility to ensure that you obtain any approvals for amendments or extensions from the NHS or Social Care. Copies of these approvals must also be sent to the FREP administrator.

It is **essential** that your FREP holds a record of all NHS and Social Care research.

3.3 Sponsorship for NHS and Social Care research

All NHS and Social Care research requires a Sponsor. This includes research that falls under the Human Tissue Act (2004) or Mental Capacity Act (2005), even if it is not taking place in the NHS. The School of Health defines a Sponsor as the 'organisation … that takes on responsibility

for confirming there are proper arrangements to initiate, manage and monitor, and finance a study'.

Anglia Ruskin University is able to act as Sponsor or Co-Sponsor in the majority of cases.

Your FREP Chair can determine whether Anglia Ruskin University is able to act as a Sponsor for your research; please send your Stage 1 Research Ethics Application Form, external application form and supporting documentation to them for review. Further documents may be requested by your FREP.

Further information regarding the responsibilities of a sponsor is available via:

http://www.hra.nhs.uk/resources/before-you-apply/roles-and-responsibilties/sponsor/

and the UK Framework for Health and Social Care Research;

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

3.4 The NHS Research Passport Scheme

If you are carrying out research involving the NHS, you may require a Research Passport. This is the mechanism for non-NHS staff to obtain an honorary contract or letter of access when they propose to carry out research in the NHS, avoiding multiple checks and speeding up the process for gaining permission to undertake research. It **does not** replace the need to obtain Health Research Authority Approval, NHS Research Ethics Committee or any other regulatory approvals required.

Please refer to the Health Research Authority's website at:

https://www.hra.nhs.uk/planning-and-improving-research/best-practice/research-passport/

Please also refer to the Research Passport Policy and Guidelines, on the Research Ethics website.

The Research Passport form is completed by the researcher and by Anglia Ruskin University and presented to all relevant NHS R&D Offices. Students' forms will need to be signed by staff from Admissions, their Supervisory team and occupational health. Members of staff will require signatures from HR Services, their line manager and occupational health.

If your research requires an NHS Research Passport, please also let the FREP administrator know, stating whether this is a project-specific or three-year passport.

3.5 Security-sensitive research

Please refer to the Guidance for Security Sensitive website at www.aru.ac.uk/researchethics

3.6 Ministry of Defence Research Ethics Committee (MODREC)

The Ministry of Defence Research Ethics Committee (MODREC) ensures that all research involving human participants either undertaken, funded or sponsored by MOD meets nationally and internationally accepted ethical standards.

Ethical approval from the MODREC is regarded as equivalent to that from Anglia Ruskin University. You still need to submit the Stage 1 Research Ethics Application Form at the earliest opportunity, along with copies of the MODREC approval documentation, to your FREP/SREP administrator when received. No formal approval is required from your FREP/SREP, but you should wait for the administrator's acknowledgement before starting your research.

If your research involves **former** members of the Armed Forces (i.e., veterans, ex-services personnel) and is not conducted on MOD premises, there is no need to seek ethical approval from MoDREC, although you must still submit Stage 1 and 2 ethical approval forms.

Please also note that the MODREC is also recognised as an Appropriate Body under the Mental Capacity Act 2005 for review of research involving UK Armed Forces personnel who are unable to consent for themselves.

For further information please see: https://www.gov.uk/guidance/apply-for-ethical-approval-for-mod-research-involving-humans

For queries, please contact Mrs Toni Mawoyo, Project Manager, Veterans and Families Institute, on email address antoinette.mawoyo@aru.ac.uk.

3.7 Approvals for research in the criminal justice system

Please refer to the guidance from the Offender Health Research Network regarding health research in the criminal justice system:

http://www.ohrn.nhs.uk/

Please contact Charlotte Lennox on email address charlotte.lennox@manchester.ac.uk for further information regarding this

and also the Research Ethics Guidebook:

http://www.ethicsguidebook.ac.uk/Prisoners-young-offenders-or-probation-services-194

Research that involves prisons, youth offending or probation services requires approval through the National Offender Management Service (NOMS).

https://www.gov.uk/government/organisations/national-offender-management-service/about/research#research-application-process

Research that is national in scope also requires Ministry of Justice approval, which can be secured through the Integrated Research Application System (IRAS).

Please speak to your FREP Chair regarding whether ethical approval from Anglia Ruskin is also required. In cases in which research governance, as opposed to ethics approval, is obtained, approval is likely to be required from your FREP. In some instances the external agency may require that university research ethics approval is obtained.

3.8 Research in courts and tribunals

If you would like to carry out research in courts and tribunals, you need to make sure that you have the necessary permissions for access to data. Please see.
https://www.gov.uk/guidance/access-to-courts-and-tribunals-for-academic-researchers

You will still need to apply for ethical approval from Anglia Ruskin.

3.9 Research taking place outside the UK

If your research is to take place outside the UK, you should refer to Anglia Ruskin University's 'Overseas Travel and Overseas Placements Policy' in the first instance, available at:

https://my.anglia.ac.uk/sites/travelform/default.aspx

If you are travelling outside the UK for the purposes of the research, you must complete a Risk Assessment (Health & Safety). Please refer to Section 3.13. You must take into account whether there is any military conflict, political sensitivities or other known problems in countries (or regions of countries) you intend to visit and if so clearly state this in the ethics application. In the case of countries or areas where the Foreign & Commonwealth Office (FCO) advises against travel, approval will normally be refused unless there are mitigating circumstances. Where these exist, written permission from the Dean must be obtained before FREP/SREP approval is granted.

Where you are working overseas with an organisation, such as an aid agency, that has its own security and evacuation procedures, it should be clearly stated in the ethical approval application if the researcher will be subject to these procedures.

You must ensure that you comply with any local laws relating to research and obtain any local ethical approval or other permissions required. The International Compilation of Human Research Standards, available here: http://www.hhs.gov/ohrp/international/index.html may be of assistance.

Should no local ethical approval be required, please state in your application for ethics approval at Anglia Ruskin that you have clarified this. If you do need local ethical approval, you will need to submit copies of your application and your approval letter(s) with your Anglia Ruskin application for ethics approval for research falling under the red category and you are strongly advised to do the same for projects in the tallow category. You need to wait until you have both local ethical approval (if applicable) and approval from Anglia Ruskin University prior to starting your research.

If there is any conflict between the ethical requirements of Anglia Ruskin University and other local or organisational ethical requirements where you are undertaking your research, please let your FREP/SREP know as soon as possible and prior to starting your research.

You must also make it clear on your application form if you are familiar with the cultural norms and language(s) of the country you intend to visit. Researchers should be of at least level 2 competency in the native language(s). For more information, please see http://www2.warwick.ac.uk/fac/arts/languagecentre/lifelonglearning/levels. If you are not at this level, a professional interpreter must be employed.

You must also ensure that you comply with data protection legislation. All research a) taking place in the European Economic Area (EEA) or b) taking place outside the EEA but you are bringing raw data back to the EEA, must comply with the General Data Protection Requirement (GDPR) and any other data protection legislation for that country. For countries outside the EEA, you must comply with all relevant data protection legislation of that country or countries. Please refer to the Data Protection Guidance on the research ethics website at www.aru.ac.uk/researchethics

You must ensure that you comply with export controls from the UK and obtain a licence if required. For further information see: https://www.gov.uk/guidance/beginners-guide-to-export-controls. Local export controls may also apply.

3.10 Research visas and permits

It is your responsibility to ensure that you obtain any visas, permits or similar documents required to allow you to carry out research in your chosen country or countries. For some countries, you are not allowed to carry out research on a tourist visa, but must get a specific one for research.

You must ensure that you are familiar with all the conditions of such research permits and visas and comply with these. If you require a research visa, you need to start preparing as early as possible, as it can take a considerable amount of time to get appointments with the necessary authorities and for the correct documents to be provided. You must also ensure that you obtain any other permission from the government, authorities or agencies in the country where you intend to carry out research.

3.11 Travel insurance

All Anglia Ruskin staff and students who are travelling overseas for their research must complete a travel registration form, at: https://my.anglia.ac.uk/sites/travelform/default.aspx. This also applies to students at our joint ventures in Peterborough and King's Lynn.

Students at other Associate Colleges need to check what their local arrangements are. Further information about which of our Associate Colleges are covered by Anglia Ruskin's travel insurance policy can be found at:

https://web.anglia.ac.uk/anet/staff/sec_clerk/Documents/Insurance/travel_ins.phtml

3.12 Additional insurance

Generally speaking, Anglia Ruskin University's insurance covers freehold buildings, staff and students, within ARU's companies including wholly owned subsidiaries. This includes our joint ventures in Peterborough and King's Lynn, LCA London Limited (ARU London Campus) arrange their own cover.

In most cases, once you have obtained ethical approval, you will be covered by Anglia Ruskin University's insurance. In some cases, however, you may require additional insurance. A questionnaire and flow chart is available on the research ethics website to help you establish this. If you think you may need additional insurance, please email Andy Chapman, Corporate Risk and Compliance Officer, at andrew.chapman@aru.ac.uk your Stage 1 Research Ethics Application Form and the completed insurance questionnaire and wait for his response before proceeding further.

If additional insurance is required please speak to your Supervisor/Line Manager/Faculty Director of Research or Research Students as a matter of urgency to establish whether your School/Faculty will fund any costs that may be incurred.

If you have any concerns about who or what is insured, you should contact Andrew Chapman, address above.

3.13 Risk Assessment (Health and Safety)

You are required to declare, as part of Section 6 of the Stage 1 Research Ethics Application Form, that you have completed a Risk Assessment (Health & Safety) if required. This mostly addresses the risks to researchers themselves of undertaking the research (for example, physical threat or abuse, psychological trauma or accident) but can also include risk to the researcher (for example, because of the potential to be caught in a compromising situation or being accused of improper behaviour) or causing physical or psychological harm to others.

If there are any significant potential risks, including lone working, overseas travel or any others hazards that could arise from your research, you **and** your Supervisor or line manager must complete the Risk Assessment (Health and Safety).

Where overseas travel is involved, researchers are expected to take into account advice provided by the Foreign & Commonwealth Office (FCO) as part of their Risk Assessment. On arrival in the country, the Risk Assessment must be reviewed and updated if required.

The FREP/SREP will not normally ask to see the Risk Assessment; however, it must be approved by your Faculty Dean. Supervisors should keep a copy of the Risk Assessment on file for their students, and Line Managers must do the same for staff. As part of the Stage 2 Research Ethics Application Form you will be required to explain any potential risks you have identified to yourself or your co-researchers and the steps you will take to mitigate them.

Once a Risk Assessment has been completed, a list of procedures should be developed to address the risks identified.

Please note that our Risk Assessment process applies to researchers based at Anglia Ruskin and our joint ventures at Peterborough and King's Lynn. If you are at another Associate College you will need to follow their research assessment process.

The Risk Assessment form and an exemplar are available on the Research Ethics website. If you have any questions contact Risk Management via riskmanagement@aru.ac.uk or via 01245 684239.

If you are carrying out research in another organisation, you need to check whether they have a risk management policy that you also need to adhere to.

3.14 Risk Assessment (Project)

A risk assessment for the project, (e.g. whether it will be completed in the timeframe) must be completed for all externally funded research if the funding was gained via Anglia Ruskin University. If this applies, you are required to declare, as part of Section 5 of the Stage 1 Research Ethics Application Form, that you have completed a Project Risk Assessment.

Please see the http://web.anglia.ac.uk/anet/rdcs/compliance/index.phtml in the first instance. If you require further information, please contact Carole Randall, Head Post Award and Commercialisation on email address carole.randall@aru.ac.uk.

3.15 Access to, and storage of, research data

It is essential to store, and allow access to your research data, appropriately, as detailed in the Research Checklist for Data Protection (which you need to complete as part of the Stage 1 Research Ethics Application Form process).

Regardless of the nature of your research data, you should make sure you keep up to date copies, so that should something happen to your working copies, your research is not adversely affected.

Please also refer to our IT Acceptable Use Policy at:

http://web.anglia.ac.uk/it/policy.

You should also note that, increasingly, research funders and publishers are expecting data generated from research and supporting publications to be made openly available, where it is appropriate to do so. This may also require you to treat your data in certain ways to enable its future reuse. Participants must also give consent for this. Please see:

http://web.anglia.ac.uk/anet/rdcs/research/data_management.phtml

3.16 Equipment checks

Electrical or other safety checks must be carried out on any equipment prior to it being used, if it has not already undergone appropriate checks by Anglia Ruskin University/your own institution. If you are at another institution, please check their requirements. Equipment must also be maintained and have regular checks throughout the course of your research, as required. Researchers must be trained in the use of any equipment and updates provided, as required. You need to check that any device you use does not fall under the Medical Devices Regulations (2002), as amended. Please see:

https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr

3.17 Permission from external organisations in which you are carrying out research

If you are carrying out research in other organisations, you must obtain permission in writing from a person in authority at the organisation, for example a head teacher at a school or company director. This must include permission for your use and ownership of data and your right to publish findings. If you plan to use the name of the organisation in the dissemination of your research, you must also have permission for this. If there is any possibility of the organisation being identified, even if their name or other key information is not used, this must be acknowledged. This is to try and avoid potential problems later on, for example organisations later refusing permission for the data to be used.

There is a template letter on the research ethics website which you may find useful.

Please note that even when you have obtained written permission, you may also need to seek verbal permission from managers at less senior levels, for example to facilitate access to the organisation, and you still need consent from participants.

3.18 Permission from archives in which you are carrying out research

If you are using data from private archives, you must have a written agreement with the owner/controller of the material regarding copyright, rights of publication, and the uses you intend to make of the material and the nature of any anonymising strategies you intend to implement. Even for public archives, there may be issues regarding ownership, publication and confidentiality that require explicit agreement. If the data relates to people who are dead, you must consider the feelings of any living relatives and whether permission is required from them.

If researching documents online that are in the public domain, you need to consider whether you still need to obtain written permission from the organisations holding them.

3.19 Internet-based research

If using the internet to carry out your research, you must read the terms and conditions of internet sites carefully beforehand, to ascertain ownership of the data, whether you are permitted to use it and whether there are any conditions regarding using it. Please refer to the Association of Internet Researcher's website at:

https://aoir.org/

3.20 Research involving Drones

For any proposed research involving Drones, please refer to Anglia Ruskin's *Flying of a Remote Controlled Aircraft (Drones)* policy:

https://web.anglia.ac.uk/anet/staff/sec_clerk/RiskManagement/HealthAndSafetyPolicies.phtml

3.21 Professional Codes of Practice and/or Conduct, and funding body requirements

You must ensure that you comply with any professional codes of practice and/or conduct that apply to your field of research. If you are a student, you are advised to discuss this with your Supervisor.

If your research has been funded, you must ensure that your research complies with any ethical requirements of your grant funder. Increasingly, grant funders have other requirements relating, for example, to open access publication of research outputs and underpinning data. Requirements relating to data must be addressed in your ethics approval application.

If your research data is to be held in an open access data repository, you must ensure that participants are informed about and consent to this. Also, please refer to the Concordat on Open Research Data:

https://www.ukri.org/files/legacy/documents/concordatonopenresearchdata-pdf/

3.22 Intellectual property

If any intellectual property could arise from your research, you must ensure that this is addressed at the earliest point. Please see our Intellectual Property Guidelines and Policy at:

http://web.anglia.ac.uk/anet/rdcs/compliance/forms.phtml

If you have any enquiries about intellectual property please contact Carole Randall, Head Post Award and Commercialisation, on telephone number 01245 684310 or email address carole.randall@aru.ac.uk

Ethics Training Requirements

4.1 Research ethics training for Undergraduate and Masters students and their Supervisors

All Undergraduates and Masters students at Anglia Ruskin and our Franchise Associate College who are required to submit an application for research ethics approval (see Section 1.1) must complete *Introduction to Research and Professional Ethics* course, which is available at: http://vle.anglia.ac.uk/sites/research_ethics.

Supervisors of Undergraduate and Masters students at Anglia Ruskin also required to complete this course. Please note that this does not apply to Supervisors at our Associate Colleges.

At the end of the course you must take the quiz, achieve at least 70% and take a screen shot of the confirmation of passing. Instructions for how to do this are in the course,

Students must submit this confirmation with their ethics application, in addition to declaring that they have completed the relevant training in research ethics. Supervisors must send this confirmation to their FREP Administrator to record.

4.2 Research ethics training for postgraduate research students and their Supervisors

Research ethics training is compulsory for postgraduate research students and their Supervisors. Please refer to the relevant sections for the Research Degree Regulations, available here: https://web.anglia.ac.uk/anet/rido/docschl/index.phtml for further information.

You are required, in Section 6 of the Stage 1 Research Ethics Application Form, to declare that you have completed the relevant training in research ethics.

4.3 Research ethics training for ethics committee members

REC, FREP and SREP members are required to complete the online training for Undergraduates and Masters students (*Introduction to Research and Professional Ethics*), available at: http://vle.anglia.ac.uk/sites/research_ethics and

either the Introduction to *Research Ethics and Integrity* session run by the Doctoral School

or the Epigeum module *Ethics 1: Good Research Practice*

and the Epigeum module *Ethics 2: Research with Humans in the Health and Social Sciences.*

In addition, SREP members must attend a mandatory two hour staff development session co-facilitated by the relevant FREP Chair and the Research Ethics & Integrity Manager. SREP members will be required to engage in CPD activity every two years thereafter.

4.4 Safeguarding training

If you are carrying out research with children or vulnerable adults, you may need to complete the online Safeguarding course, available at:

https://angliaruskin2.learnupon.com/.

At the end of the course, you must take the quiz, achieving at least 70%, confirmation of which must be submitted with your ethics application. If you have any problems accessing the course, please email research.ethics@aru.ac.uk.

If you have significant experience of working with children or vulnerable adults, you can request course exemption from your FREP Chair.

Key issues to consider in your ethics approval application

5.1 Selection of participants

The ethics committee will need to be assured that you have given careful consideration to the selection of your participants. For example, you will need to justify your sampling technique or inclusion and exclusion criteria for participants.

If your research will take place in the UK, you must ensure that your selection of participants complies with the General Data Protection Requirement (GDPR) and Data Protection Act (2018).

If your research is outside the UK but in the European Economic Area (EEA), you need to comply with the GDPR and any other data protection legislation relating to that country or countries.

If your research will take place outside of the EEA, you need to comply with any data protection legislation for that country.

Should your research be taking place outside the EEA, but you will bring your data back to the UK, the GDPR and Data Protection Act (2018) will apply.

Should your research be taking place outside the EEA, but you will bring your data back to the EEA, the GDPR and any further data protection legislation of that country will apply.

Should you be transferring any data out of the EEA, the GDPR will apply along with any data protection legislation for that country.

Please refer to the Data Protection Guidance on the research ethics website at www.aru.ac.uk/researchethics for further information. If you have any further queries, please contact our Data Protection officer at dpo@aru.ac.uk

If you will be carrying out research in an organisation, you need to give due consideration to how you will access potential participants. You will not be able to obtain details of individuals held by another organisation without the prior permission from those individuals, unless their names are already in the public domain. In such cases, the initial approach to participants will probably need to come from someone working at that organisation and any documentation must make it clear it is from them, rather than sent by you directly. Even if you work at the organisation involved and already have access to details of individuals, this does not automatically mean that you are allowed to contact them for research purposes. You must check with a senior manager.

If your research is internet-based, how can you be sure that participants are who they claim to be? For example, can you be sure that they are all aged 18 years and over, or located in a specific place, given world-wide access to the internet. If appropriate for your research, you may consider gaining permission from an organisation regarding advertising for participants on their website. You also need to comply with terms and conditions of the website.

You should try to avoid involving potential participants who are unsuitable. For example, if you are using a poster to recruit participants, it makes sense to clearly identify any exclusion criteria on it. Try not to ask people to complete a questionnaire to establish whether they meet the inclusion criteria. Find another way to screen these people out to avoid wasting their time.

5.2 Informing your participants

You must ensure that you include all relevant information about your research and explain clearly what participants will be asked to do on the Participant Information Sheet. Participants should be told why they have been selected to take part and how many people have been approached.

a) Checking understanding

You must ensure that people understand what they are being asked to do. You could do this by asking them questions about what is on the Participant Information Sheet, to help establish that they understand it.

b) Research using anonymous questionnaires

When your study involves a questionnaire which participants will return anonymously, you must still provide participants with relevant information about your study, although you may choose to incorporate it into the questionnaire rather than using a separate Participant Information Sheet. When data is anonymised, it no longer falls under the General Data Protection Requirement (GDPR) and Data Protection Act (2018). You do, however, need to be certain that it is truly anonymised if claiming this is the case. Please refer to the Data Protection Guidance on the research ethics website at www.aru.ac.uk/researchethics for further information.

c) Using Online Survey Platforms

Please refer to the Guidance for Online Surveys on the research ethics website at www.aru.ac.uk/researchethics

If you are based in the UK, it is advised that you use Online Surveys:

https://www.onlinesurveys.ac.uk/

Please contact Emma Marrow at emma.marrow@aru.ac.uk who will set up and account for you.

d) Inclusivity

Please ensure that your documentation is inclusive. Spell out any acronyms the first time you use them in your application. Avoid the use of jargon. It may be useful to show your Participant Information Sheet to a friend or a colleague who is not in your field, to check that it is easily understood.

If your research sample is likely to include people who cannot speak or write English, the documentation needs to be translated and this may require consideration of cultural norms. Researchers must be of at least level 2 competency in the native language of their participants. See http://www2.warwick.ac.uk/fac/arts/languagecentre/lifelonglearning/levels. If you are not of at least level 2 competency, you must employ a professional translator and ensure that all documents are translated.

You also need to consider people with special needs (for example, visual impairments, dyslexia) and the provision of documentation in alternative formats.

e) Anonymity

All data you collect should be anonymised if possible. However, information that could identify people is not limited to their names, and it is sometimes possible with case studies or interview transcripts that people may be identified, by their peers if not by the general public, even if every effort is made to remove all identifying information relating to participants prior to dissemination. If this is the case for your study, it needs to be made explicit in the Participant Information Sheet

that there is a possibility that participants could be identified in dissemination. Guard against making unrealistic assurances to participants about data being anonymous.

When data is anonymised, it no longer falls under the data protection legislation. It can, however, be difficult to establish if data is truly anonymised. Please refer to the Data Protection Guidance on the research ethics website at www.aru.ac.uk/researchethics for further information. You also need to take into account that someone could potentially be identified through linking together pieces of information about them you hold with freely available information on social media, for example (e.g. Motivated Intruder Test, please see https://www.ucl.ac.uk/legal-services/guidance/gdpr-anonymisation-pseudonymisation)

If you will be making use of personally identifiable information in dissemination, for example photographs, special care must be taken. You should give participants the opportunity to consent to each new occasion these will be used. When you are doing research using the internet, even more care must be taken, for example search engines could be used to find the source of quotes.

If you will be using direct quotes from participants in your dissemination, or recording using audio or visual equipment, this must be stated on both the Participant Information Sheet and as one of the statements on the Consent Form.

f) Access to, storage of and destruction of data

All participants must be informed at the outset what personal data (or special category data) will be required from them and what this data will be used for. They will also need to know how long the data will be kept for, who will have access to it (for example, the research team) and how it will be stored, including whether it will be anonymised for storage. You must make these arrangements clear on the Participant Information Sheet. There is a template Participant Information Sheet that Undergraduate and Masters students are advised to use, which contains this information and some Data Protection text that is mandatory for who does not use the template. Both of these are available on the research ethics website at www.aru.ac.uk/researchethics

g) Participants' attendance

If the research will involve participants having to travel to where the study will be carried out, this must be made explicit on the Participant Information Sheet, including how many visits will be required, how frequent they will be and whether travelling expenses will be reimbursed. It may not be possible to reimburse travel expenses, in which case this must be stated on the Participant Information Sheet.

h) Transcription service

If you will be employing a transcription service to transcribe interviews, for example, people must give consent for this – you need to include information about this on the Participant Information Sheet and provide a separate statement on the Consent Form. You also need to ensure compliance with GDPR – please contact our Data Protection Office on dpo@aru.ac.uk

i) Sharing results with participants

It is good practice to offer to send participants a summary of your general research findings. This should be factored in at the planning stages of your research.

5.3 Consent

This is an important area and one that the FREP/SREP will focus on when reviewing your application. Participants must have the capacity to consent, and that consent must be informed and freely given. There must be no coercion. Participants should also be given adequate time to decide whether they wish to take part and have the opportunity to discuss the research with family and friends first, should they wish.

a) Capacity to consent

Your participants must normally have the capacity to give informed consent to participate in your research.

If you are carrying out research with vulnerable groups who do have capacity to consent, this can be reviewed by your FREP. You must, however, provide written information about how you will ensure participants are able to consent and therefore do not fall under the remit of the Mental Capacity Act (2005).

If your research is taking place in England or Wales and one or more participant is unable to consent, the research falls under the Mental Capacity Act (2005) and legally can only be reviewed by a Research Ethics Committee recognised by the Secretary of State or Welsh Ministers. University Research Ethics Committee cannot legally review research falling under the Act. You also need to be aware of and comply with the equivalent legislation in Scotland and Northern Ireland. Please refer to Section 6.2.

b) Children's consent

The principles that apply to research with adults, as noted above, apply equally to children, but there are four additional provisos. Researchers must bear in mind the child's competencies, perceptions and frameworks of reference, which may differ between different children, and adults, because of factors including, but not only, age. Children may be more easily exploited in interacting with adults, who have specific responsibilities towards them. There are different power relationships between adults and children. Finally, the role of adult gatekeepers may be important.

You may need to obtain gain initial permission from an adult gatekeeper – for example, a teacher, for the research. This permission does not constitute consent, but allows you to seek consent from the children and parents.

You should get active consent from each individual child – as with adults, you should assume that child is able to consent, but you may need to adapt your methods in seeking consent to get informed consent from a child. This might involve special versions of your Participant Information Sheet which are more easily accessible to children. These will need to be prepared taking the age of participants into account. Please see the Faculty of Health, Education, Medicine's website for examples of Participant Information Sheets for children of different ages,

You would normally obtain verbal rather than written consent from children.

Bear in mind that there is a difference between consent for research, and consent to medical treatment, including clinical research trials. Parents have responsibility in law for their child, up to the age of 18 years in England, Wales and Northern Ireland, and up to 16 years in Scotland. It is usual for adult consent to be sought for research with children.

For more information see the http://www.ethicsguidebook.ac.uk/research-with-children-105.

c) Participants in organisations

For research taking place in an organisation, you must consider whether participants may have been told they should take part in the study by management. The requirement for voluntary consent without coercion can be aided by providing an information pack to the organisation, with clear recruitment procedures, that make it clear that people should not take part if they do not wish to and that they can withdraw at any time.

d) Withdrawal from the study

Participants have the right to withdraw from the study at any time, without providing any explanation. You need to make it as easy as possible for people to withdraw, bearing in mind that they might not feel comfortable telling you directly that they no longer want to participate. At the start of the study, you could provide participants with a form to email or post you saying they would like to withdraw. Participants may also give you cues that they would like to withdraw, for example not turning up for interviews or giving short answers and it is important to be sensitive to these.

You also need to consider whether the data participants have provided would still be useful if they decide to withdraw before the end of the study. If this is the case, they will still need to consent to its use. You can therefore give participants the option to withdraw and also have their data withdrawn, or to withdraw but state that they are still happy for their data to be used. Participants may also choose to withdraw their data from the study. It is good practice to notify all participants of the last date it will be possible for them to withdraw their data (for example, prior to writing up your dissertation or for publication).

If you are carrying out a focus group, it will not be possible to withdraw one person's data without removing the data for all participants, because what one person says will affect the responses from others. You must therefore make it clear on the Participant Information Sheet that it will not be possible to withdraw data in this case.

If you have anonymised data, it will not be possible to withdraw someone's data as you will not know which belongs to them. You therefore need to make this clear on your Participant Information Sheet.

e) Asking participants for information about other people

If you are carrying out research that involves asking participants about other people, you must consider whether you need to also obtain consent from them. Even if participants are disclosing information about family members, you must not assume that this is ethically acceptable.

f) Research using questionnaires

If you are asking people to complete a questionnaire which will be anonymous, consent can be implied by its return. You do not need to also ask participants to complete a Consent Form. It is, however, good practice to include general statements taken from the template Consent Form in your questionnaire, and ask participants to check a box for each one to confirm that they are happy to participate.

g) Internet-based research

Although what people say online, for example in chat-rooms on internet sites, is technically in the public domain, this does not mean that it would be ethical to use it for research, as people may not expect their comments to be used in this way. It may, however, not be possible to obtain consent from such people and, if this is the case, you need to justify the approach that you have used, in particular relating to the anonymity of participants in dissemination.

h) Forms of consent

Obtaining written consent should be your default position. In some cases, this may not be possible or not appropriate, perhaps because of the participants or their cultural norms. Verbal consent, if it sought, should be audio-recorded or witnessed. You need to justify to the FREP/SREP why you are not planning on obtaining written consent.

i) Studies where it is not possible to obtain consent

Obtaining consent from participants must be your default position. For some types of research e.g. covert observation, it will not be possible to obtain consent, but your approach must be justified and any potential harm to participants arising from the study carefully considered.
Your study may involve existing data sets that will have been gathered without consent from the participants for your study. Often these data sets are so large and anonymous that this poses low ethical concerns. It is, however, of more concern in circumstances such as:

- Data to which you have access solely by virtue of a non-research role e.g. through employment. This might be clinical data if you work in such a setting, or commercial data in business research.
- Data accessed through the internet e.g. analysis of social network sites, even if identities are not recorded with the data.
- Intensive data gathering and data linkage and aggregation from data sets, including those publically available, may allow individuals to be identified by those with access to the collated data.
- Novel use of existing data that might have given participants reasons to object if they had known about it when they provided consent.

In these cases you will need to think carefully about whether you need to adjust your procedures or how you can justify them ethically. You should also contact our Data Protection Officer at dpo@aru.ac.uk if there is uncertainty this will comply with data protection legislation.

5.4 Disclosure

One issue that arises fairly frequently in research is whether information that is revealed during the course of the study should be disclosed, either to the participants themselves or to third parties. The FREP/SREP will want to be certain that the researcher has weighed up the various factors involved and that their approach to disclosure is justified. This will serve to reduce the risks to the researcher, as problems are less likely to occur later on.

Students must always notify their Supervisors should issues of disclosure arise and all researchers must notify the appropriate FREP/SREP. Even when all factors have been addressed in detail beforehand, situations may arise when it is not clear whether disclosed information should be passed on. Such cases should be discussed by the research team/students and Supervisors and referred to the FREP/SREP immediately.

When working with a group of participants where disclosure is more likely to occur, there should generally be a clause on the Participant Information Sheet stating that if certain details are revealed, they will need to be passed onto third parties.

The decision whether to disclose needs to be considered on a case-by-case basis for each research project. Researchers also need to ensure that they are complying with any professional codes of practice or any policies within the organisation in which they are working and also data protection legislation.

A need to disclose may arise in a variety of situations, as discussed below.

a) Incidental findings of medical investigations

Although it may seem that participants should always be informed about abnormalities found in medical tests, this needs to be balanced against their autonomy (and their right not to be given findings if they do not wish to be). Implications for family members or partners (for example, in the case of genetic conditions or sexually transmitted infections) also need to be taken into account.

Another consideration is whether the researcher is qualified to interpret the results and the further support that is available for the participant (e.g. his/her GP, counselling). It should be

made clear that the findings indicate a problem that requires further investigation, rather than being a formal diagnosis, unless this is the situation.

A further consideration is if the researcher is passing on information about a potentially serious medical condition. Does the researcher have the expertise to do this and how much support should he/she be providing to the participant before referral to another party? How quickly will this further support be available if the findings are highly distressing for the participant? There may be an impact on the participant's insurance or future employability as a result of the findings and these types of issues need to considered at the planning stages of the research and included on the Participant Information Sheet.

b) Participants expressing the intent to harm themselves or others

The measure that has been used to obtain the information is important. If the results of a questionnaire have suggested, for example, intent to self-harm, how robust is this measure clinically? The researcher may be seen to have a duty of care or professional responsibility to pass this information on to a third party (for example, the person's doctor/GP), but the point at which this should occur may not always be clear. As well as providing details in the Participant Information Sheet, researchers should discuss their intentions to pass information on to third parties with participants.

c) When illegal activities by participants are revealed

The issue of disclosure becomes even more complex in the area of illegal activities. When a researcher is working with certain groups of participants, for example people who take illegal drugs, this issue will arise. Clearly, a great deal of valuable research takes place within these areas, but the legal and ethical issues must be carefully addressed beforehand.

In general, there is no legal obligation to report an offence (except in certain terrorism and money laundering cases), but careful consideration of the Serious Crime Act (2007) should be undertaken by the researcher. This Act deals with offences such as assisting or encouraging an offender, which may impose a duty to act in order to avoid liability. Legal advice may need to be sought.

d) If unethical practice is revealed by staff working at organisations where the research is being undertaken.

In the instance of an employee revealing unethical or bad practice, this should generally be disclosed, but there are also a number of factors that need to be considered. Is the researcher also employed at the organisation? Is the bad practice likely to be dangerous, for example, if the research is taking place in a medical setting, or illegal (e.g. fraud)? Who should the information be disclosed to? Are there any negative consequences that may arise for the researcher if he/she does this, for example, if he/she works at the organisation?

Legislation relating to research ethics

It is your responsibility to be aware of all legislation relating to your research and ensure that you comply with it. . For research outside the UK, you need to be aware of and comply with the laws of the host country and possibly with UK laws as well. If there is any conflict between legislation and your conditions of ethics approval, please refer to the FREP/SREP Chair immediately. Some of the key legislation follows; please note that this is not an exhaustive list.

If your research falls under legislation, the FREP/SREP will want to see that you are familiar with the legislation and evidence that you will adhere to it. It is also your responsibility to be aware of any legislation that comes into force during your research. If this requires further changes to your research, you must apply for approval for these revisions, as with any other amendments (see Section 2.10).
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6.1 Data Protection Legislation

Please refer to the Data Protection Guidance on the research ethics website for further information about the General Data Protection Requirement (GDPR) and Data Protection Act (2018).

If you have any queries relating to any data protection issues you can contact our Data Protection Officer at dpo@aru.ac.uk

You can also find further information on the Information Commissioner's Office website at:
https://ico.org.uk/

6.2 The Mental Capacity Act (2005)

The Mental Capacity Act applies to England and Wales only, and is available here:
https://www.gov.uk/government/collections/mental-capacity-act-making-decisions

In Scotland, the inclusion of adults lacking capacity in research is governed by the provisions of Section 51 of the Adults with Incapacity (Scotland) Act 2000. In Northern Ireland, it is currently governed by the Mental Capacity Act (Northern Ireland) 2016.

The Mental Act generally relates only to people aged 16 years and over, to empower and protect people unable to make their own decisions, for example, relating to property and financial affairs or healthcare treatments. It also covers 'intrusive research' (i.e. that which would have normally required consent). The 'ill treatment' or 'wilful neglect' of people who lack capacity are criminal offences under the Act which carry a penalty of up to five years' imprisonment.

The five key principles that underpin the Act are:

- a presumption of capacity (the starting point is that people have the right to make their own decisions)
- people have the right to be supported to make their own decisions
- people should be allowed to make what may be viewed as unwise decisions
- anything carried out for or on behalf of people who do not have capacity must be in their best interests
- the least restrictive option, in terms of people's rights and freedom of action, must be taken.

There are a range of factors that can cause incapacity, including learning disabilities, dementia and mental health problems. Loss of capacity can also be temporary, for example due to shock or the effects of drugs or alcohol. Capacity is measured using a two-stage test:

- Is there an impairment or disturbance in the functioning of the person's mind or brain?
- If yes, is this sufficient to cause the person to be unable to make that particular decision at the relevant time?

If the answer is yes, the research will need to meet all the requirements of the Mental Capacity Act. The ability of a person to make a decision should be assessed in each different situation. It is important to acknowledge that people may have the capacity to make some decisions, but not others, or their ability to do this may fluctuate over time.

The Act is accompanied by a statutory Code of Practice providing guidance on how it should be used.

University research ethics committees are not authorised to review research that falls under the Act. The research can only be approved by a Research Ethics committee recognised by the Secretary of State or Welsh Ministers:

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/mental-capacity-act/

The Ministry of Defence Research Ethics Committee (MoDREC) is also recognised as an Appropriate Body under the Mental Capacity Act 2005 for review of research involving UK Armed Forces personnel who are unable to consent for themselves.

Please see:

https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/non-nhs-research-ethics-committees/

Researchers who carry out research within the remit of the Act are also legally required to adhere to the Code of Practice, available at:

www.justice.gov.uk/protecting-the-vulnerable/mental-capacity-act.

The Office of the Public Guardian's website at www.publicguardian.gov.uk may also be useful.

6.3 The Medical Devices Regulations (2002) as amended and Medicines for Human Use (Clinical Trials) Regulations (2004) as amended

We do not currently have the infrastructure to sponsor research falling under the Medicines for Human Use (Clinical Trials) Regulations (2004) as amended or Medical Devices Regulations (2002) as amended.

Please also see the Medicines and Healthcare's Product Agency's website at:

www.mhra.gov.uk/index.htm

Any research and development activity related to medical technology and devices may fall into the remit of regulations for medical devices (MDR) and in vitro diagnostic medical devices

(IVDR). In such a case, it is the University's responsibility to notify the UK Regulator (Medicines and Healthcare Products Regulatory Agency; MHRA).

For clarity purpose, a medical device is defined as *any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:*

- *diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,*
- *investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,*
- *providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,*
- *and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means."*

For further information about what constitutes medical devices, please see the below link. Please note that devices can include apps.

https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety

If you have any query regarding whether your research constitutes a medical device, please contact ARU's Medical Technology Research Centre (MTRC) for advice, prior to making your ethics application.

https://www.anglia.ac.uk/medical-science/research/biomedical-technology-research-centre

6.4 The Terrorism Act (2006)

Please also refer to the *Guidance for researchers and supervisors for security-sensitive research* on website at www.aru.ac.uk/researchethics

Sections 2 and 3 of chapter 11 of the Terrorism Act (2006) outlaw the dissemination of terrorist publications, including by electronic means, and give a very wide definition of 'terrorist publication' and 'statements' that could be construed as endorsing or promoting terrorism. This includes the web posting of material that encourages or endorses terrorist acts, even terrorist acts that have occurred in the past.

We have implemented this aspect of the Act by building into our ethical approval procedures a requirement for researchers to a) notify Anglia Ruskin if their research could lead them to access such materials and b) keep them on a secure university server which only you and for taught students your supervisor, can access. IT will generate a weekly report to Julie Scott, Research Ethics and Integrity Manager, which will show the titles of all your documents. Please therefore ensure that you label them clearly.

In order to have a secure document store, please contact Julie Scott, Research Ethics and Integrity Manager, via research.ethics@aru.ac.uk or by telephoning 01245 684210.

We have adopted the procedure outlined in the below guidance:
Universities UK, Oversight of security-sensitive research material in UK universities: guidance (October 2012), pp 3-4, [accessed 17 March 2016] available at:

http://www.universitiesuk.ac.uk/highereducation/Pages/OversightOfSecuritySensitiveResearchMaterial.aspx.

6.5 The Counter-Terrorism and Security Act (2015)

The Counter-Terrorism and Security Act (2015) places a duty on 'specified authorities' (of which Anglia Ruskin is one) to prevent people being drawn into terrorism. This is often referred to as the Prevent Duty. However, the Act also recognises the necessity for freedom of speech in universities which may involve researchers accessing material or producing research that falls under provisions of the Act.

We have implemented this aspect of the Act by building into our ethical approval procedures a requirement for researchers to a) notify Anglia Ruskin if their research risks being construed as encouraging terrorism or inviting support for proscribed organisations, or contains extremist views that risk drawing people into terrorism or are shared by extremist groups, b) store any materials on a secure university server, c) undergo Prevent awareness training and d) specify how they will address any concerns arising under the Prevent duty.

Please refer to the *Guidance for researchers and supervisors for security-sensitive research* on the research ethics website at www.aru.ac.uk/researchethics

6.6 Counter-Terrorism and Border Security Act 2019

The Counter-Terrorism and Border Security Act 2019 updates, and closes gaps in existing counter-terrorism legislation to ensure that it is fit for the digital age and reflects contemporary patterns of radicalisation. It was introduced to the House of Commons on 6 June 2018, and received Royal Assent on 12 February 2019.

For further information, please refer to the government's website:

https://www.gov.uk/government/collections/counter-terrorism-and-border-security-bill-2018

6.7 Human Biological Material and the Human Tissue Act (2004)

Human Tissue Act
The Human Tissue Act (2004) covers England, Wales and Northern Ireland. It is available here: http://www.legislation.gov.uk/ukpga/2004/30/contents. It came into force on 1 September 2006 and is **not** limited to healthcare settings. The Act regulates the removal, retention and storage of "relevant material" from people who have died and the retention and storage of such material from people who are living (removal from people who are living is covered by Common Law). There are also codes of practice with which you need to be familiar, available from the Human Tissue Authority website: www.hta.gov.uk.

The fundamental principle underpinning the Act is 'appropriate consent' for 'scheduled purposes'. Research is defined as a scheduled purpose under the Act. Removing, storing or using human tissue for scheduled purposes without appropriate consent and carrying out licensable activities without holding a licence from the Human Tissue Authority, which has been appointed to oversee compliance with the Act, can lead to penalties including a fine and/or up to three years imprisonment.

ARU Policy for human biological material:
ARU Policy establishes standards for collecting, obtaining, using, storing and disposing human biological samples in research and teaching activities in accordance with relevant laws, regulations and ethical principles.

The Policy applies when Anglia Ruskin staff or students collect, obtain, use, store or dispose human biological material for any purpose or when Anglia Ruskin staff or students engage other parties to collect, obtain, use, store or dispose human biological material for any purpose or activity which are conducted, sponsored, supported or funded by ARU.

Any visitors who are collecting, obtaining, using, storing or disposing human biological material for any purpose or activity in Anglia Ruskin premises should be compliant with this Policy. Their ARU host will be responsible for their compliance.

Any work with human embryonic or foetal material must be compliant with Human Fertilisation and Embryology Act 2008 which is outside the scope of this Policy. Proposals to collect, obtain, use, store or dispose human embryonic or foetal material for any purpose or activity which are conducted, sponsored, supported or funded by ARU must be approved by the Secretary & Clerk.

Definition of human biological material:
Anglia Ruskin's definition of human biological material or relevant material is broader than that used by the Human Tissue Authority and includes any material that contains one or more human cells. This includes but is not limited to: serum, blood, urine, saliva, hair, nails and gametes (sperm/ egg cells). Established cell lines (e.g. HeLa), acellular derivatives (e.g. isolated proteins) and acellular preparations of human biological materials (e.g. sub-cellular fractions) are not considered human biological material under Anglia Ruskin Policy or the Human Tissue Act (2014).

Whilst DNA is not considered to be human biological material, the HTA (2004) does include specific provisions for working with DNA and any work with DNA and any work with human DNA will be considered human biological material for the purposes of the University policy.

What do I need to do if I want to collect, obtain, use, store or dispose human biological material?
Any member of staff or student who wishes to collect, obtain, use, store or dispose human biological material must apply initially to either Faculty of Science and Engineering or Faculty of Health, Education, Medicine and Social Care Faculty Research Ethics Panel.

Following ethical approval, the Panel will then forward the application to our Human Biological Material Committee.

Associate Colleges are not covered by ARU's Research Licence.

If you have any queries, please contact the HMMC at ARU-HBMC@aru.ac.uk

6.8 The Nagoya Protocol

Every country has rights over the genetic resources that exist within its borders, including animals, plants and organisms. The Nagoya Protocol is an international legal framework that enables equitable sharing of genetic material (plant, animal, microbial, other) including the traditional knowledge associated with the genetic resources, and the benefits that arise from their use.

Researchers have a legal obligation to comply with the Nagoya Protocol. The Protocol only applies to genetic resources accessed: 1) from a country that is party to the Nagoya Protocol and that has Access and Benefit Sharing legislation and 2) for the purpose of 'utilisation of genetic resources' after 12th October 2014.

The Nagoya Protocol was adopted by European legislation through Regulation (EU) No. 511/2014and came into force on 12th October 2014. It was implemented into UK law through

the Statutory Instrument No. 821 'The Nagoya Protocol (Compliance) Regulations 2015'. The legislation is implemented and enforced in the UK by the Office for Product Safety and Standards (OPS&S). For further information, please see the Government's website:

https://www.gov.uk/guidance/abs

6.9 The Genetically Modified Organisms (Contained Use) Regulations (2014)

The GMO(CU) Regulations (2014) provide for human health and safety and environmental protection from genetically modified micro-organisms in contained use, and human health and safety from genetically modified plants and animals. The key requirement of the GMO(CU) Regulations is to assess the risks of all contained uses and to ensure the sure that any necessary controls are put in place. The GMO(CU) Regulations provide a framework for making these judgments, and place clear legal obligations on people who work with GMOs.

6.10 Other UK legislative requirements

The countries of the UK differ in their legislation and this may impact on your research. For example:

- Independent Health Care (Wales) Regulations (2011)
- Independent Health Care (Northern Ireland) Regulations (2005)
- Residential Care Homes Regulations (Northern Ireland) (2005)
- Nursing Home Regulations (Northern Ireland) (2005)
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For further information please see the Health Research Authority website http://www.hra.nhs.uk/ or contact Julie Scott, Research Ethics and Integrity Manager on 01245 684210 or via research.ethics@aru.ac.uk